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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,166	03/17/2004	James Robert Schwartz	9184M	4150

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EXAMINER

ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/802,166	Applicant(s) SCHWARTZ ET AL.	
	Examiner Ernst V. Arnold	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/20/2005, 1/24/2005, 1/28/2004 11/15/05</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The Examiner acknowledges receipt of application number 10/802,166 filed on 03/17/2004. Claims 1-25 are pending and are presented for examination on the merits.

It is suggested that Applicant change the acronym for zinc pyrithione (ZPT) in instant claim 5 to zinc pyrithione for purposes of clarity.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner what constitutes an "effective amount" of zinc-containing layered material and an "effective amount" of a surfactant in instant claim 1 and an "effective amount" of a pyrithione or polyvalent metal salt of pyrithione in instant claim 2 when the claims are drawn to a composition without an intended use. The Examiner interprets the claims to read upon a composition comprising the ingredients.

Claims 3-25 are also rejected as being indefinite because they are dependent on an indefinite base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6-8, 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Cilley et al. (4,933,101).

Instant claim 1 is drawn to a composition comprising a zinc-containing layered material and a surfactant wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%. The Examiner sought guidance from the specification on the definition of a zinc-containing layered material. Applicant defines a zinc-containing layered material (Page 5, lines 11-16) as:

Many ZLM's occur naturally as minerals. Common examples include hydrozincite (zinc carbonate hydroxide), basic zinc carbonate, aurichalcite (zinc copper carbonate hydroxide), rosasite (copper zinc carbonate hydroxide) and many related minerals that are zinc-containing. Natural ZLM's can also occur wherein anionic layer species such as clay-type minerals (e.g., phyllosilicates) contain ion-exchanged zinc gallery ions. All of these natural materials can also be obtained synthetically or formed in situ in a composition or during a production process.

Applicant further provides synonyms for basic zinc carbonate (Page 6, lines 3-7):

Basic zinc carbonate, which also may be referred to commercially as "Zinc Carbonate" or "Zinc Carbonate Basic" or "Zinc Hydroxy Carbonate", is a synthetic version consisting of materials similar to naturally occurring hydrozincite. The idealized stoichiometry is represented by $\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2$ but the actual stoichiometric ratios can vary slightly and other impurities may be incorporated in the crystal lattice

Applicant provides commercial resources for basic zinc carbonate, which is provided as zinc carbonate Page 5, lines 31-33 and page 6, lines 1-2):

Commercially available sources of basic zinc carbonate include Zinc Carbonate Basic (Cater Chemicals: Bensenville, IL, USA), Zinc Carbonate (Shepherd Chemicals: Norwood, OH, USA), Zinc Carbonate (CPS Union Corp.: New York, NY, USA), Zinc Carbonate (Elementis Pigments: Durham, UK), and Zinc Carbonate AC (Bruggemann Chemical: Newtown Square, PA, USA).

Therefore, the Examiner interprets insoluble zinc carbonate particles to be a zinc-containing layered material.

Cilley et al. disclose a detergent composition comprising from about 0 to 5% detergent surfactant (instant claims 6-8); from about 0.25% to 10% of a thickening agent; and an amount of an insoluble inorganic zinc compound that will provide the composition with from about 0.01 to about 1.0% zinc (Column 24, lines 10-23). A number of zinc compounds can be used including zinc basic carbonate (Column 22, lines 50-58 and column 24, lines 30-34). The zinc compound can be zinc carbonate (Column 24, lines 35-36). An example of a composition comprising insoluble zinc carbonate particles having a particle size less than 250 microns is provided (Column 22, line 60-column 23, line 31). The surfactant is an anionic surfactant (Column 24, lines 60-64). Since the disclosure of Cilley et al. has the same zinc-containing layered material

as the instantly claimed invention then it would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than about 25% and thus meet the limitations of instant claims 1 and 12-17. The Patent and Trademark Office is not equipped with the scientific equipment to compare the composition of Cilley et al. to the instantly claimed invention but when the compositions are comprised of the exact same materials and would inherently have the exact same properties then the burden is appropriately shifted to the Applicant to demonstrate that they are not the same.

Claim Rejections - 35 USC § 102

Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151).

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from 0.001 to 10% zinc pyrithione; from 0.001 to about 10% of a zinc salt and an anionic deterative surfactant for a topical carrier thus reading on instant claims 1-3, 5, 7 and 8 (Claim 1). The zinc salt can be the insoluble particulate zinc carbonate anticipating instant claim 14 (Claim 6). Since the disclosure of Gavin et al. has the same zinc-containing layered material as the instantly claimed invention then it would inherently have the same relative zinc lability of greater than about 15% to greater than about 20% and to greater than about 25% and thus meet the limitations of instant claims 12-17. The pH of the compositions ranges from about 2 to about 10 and most preferably from about 5.5 to about 7.5 thus within the scope of instant claims 9-11

(Page 7, lines 7-9). The concentration of the anionic surfactant ranges from about 5% to about 50% by weight of the composition consequently reading on instant claims 4 and 6 (Page 8, lines 10-16). The addition of cationic deposition polymers (instant claim 18) is anticipated (Page 20, lines 30-34-page 25, line 30). The addition of conditioning agents (instant claim 19) is anticipated (Page 35, line 12- page 47, line 16). Suspending or thickening agents are anticipated and crystalline suspending agents are preferred thus reading on instant claims 20-22 (Page 18, line 27-page 20, line 28) Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence anticipating instant claims 23-25 (Claim 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17, 19-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiese (US 5,227,156) in view of Blank et al. (5,883,085).

Wiese discloses an anti-dandruff shampoo comprising up to about 40% anionic, nonionic, amphoteric and zwitterionic surfactants; from about 0.1 to about 2% zinc pyrithione; from about 0.001% to about 1% of a zinc compound selected from the group consisting of a zinc salt of an organic acid, a zinc salt of an inorganic acid, zinc oxide,

zinc hydroxide, and mixtures thereof and water (Abstract; column 1, lines 35-47; column 2, lines 1-32; column 3, lines 32-45; and claim 1, for example). Wiese discloses that a preferable pH of the composition is neutral (7.0) to slightly acidic pH, which is within the scope of the instant claims (Column 3, lines 64-66). Wiese further provides examples of shampoo compositions comprising a polymeric suspending agent, hydroxypropyl methylcellulose (Column 4, line 38).

Wiese does not expressly disclose zinc carbonate as one of the zinc compounds in the composition although Wiese does disclose zinc compounds of organic acids.

Blank et al. discloses topical skin formulations comprising zinc carbonate as a skin protectant (Column 8, lines 30-42 and claim 14, for example).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the anti-dandruff shampoo of Wiese by adding zinc carbonate as suggested by Blank et al to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Wiese suggests that zinc compounds of organic acids can be used and zinc carbonate is the zinc salt of carbonic acid. One of ordinary skill in the art would have been motivated to select zinc carbonate because Blank et al. disclose that zinc carbonate is beneficial to the skin as a protectant (Column 8, lines 30-42).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because

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every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Double Patenting

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I. Claims 1-3, 5, 14-17 and 23-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-9, 13 and 23-25 of copending Application No. 10/803,126. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention embrace or are embraced by the claims in the co-pending application as is shown in the claims analysis table below.

Instant Application 10/802,166	Common claim elements	Co-pending Application 10/803,126 (03/17/2004)
1 and 2	Zinc-containing layered material; metal salt of pyrrhione	1
1, 2 and 14	Zinc-containing material is basic zinc carbonate	1 and 5
1, 2 and 15	Zinc-containing material is basic zinc carbonate	1 and 6
1, 2 and 16	Zinc-containing material is basic zinc carbonate	1 and 7
1, 2 and 17	Zinc-containing material is basic zinc carbonate	1 and 8
1-3	Zinc pyrrhione	1 and 9
1-3 and 5	0.01 to 5% zinc pyrrhione	1, 9 and 13
1, 2 and 23	Method of treating microbial infections	1 and 23
1, 2 and 24	Method of treating fungal infections	1 and 24
1, 2 and 25	Method of treating dandruff	1 and 25

One of ordinary skill in the art would have recognized that the composition comprising a zinc-containing layered material; a surfactant; and a metal salt of pyrrhione is encompassed by the composition of the co-pending application comprising a metal salt of pyrrhione and a zinc-containing layered material. The limitations of an effective amount of a zinc-containing layered material which provides an augmentation factor greater than 1 and a relative zinc lability of greater than about 15% is deemed merely a matter of routine optimization which is well within the purview of one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

II. Claims 1-3, 5-7, 9, 14-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 38-41, 43-50 and 54-56 of copending Application No. 10/742,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention embrace or are embraced by the claims in the co-pending application.

The limitations of instant claims 1, (an effective amount of zinc-containing layered material; an effective amount of a surfactant including a surfactant with an anionic functional group; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%) 2, (wherein the composition further comprises an effective amount of a pyrithione or a polyvalent metal salt of a pyrithione; 3, (wherein the pyrithione or polyvalent metal salt of pyrithione is zinc pyrithione) and 9 (pH is greater than about 6.5) are recited in copending claims 38, 39, 44, 45, and 50. Likewise, copending claims 40 (basic zinc carbonate), 41 (amount of zinc pyrithione), 43 (suspending agent), 44-46 (surfactant), 47 (cationic deposition polymer), 48 (conditioning agent) and 54-56 (methods of treating microbial infections, fungal infections and dandruff) are obvious variants over instant claims 5-7 (amount of zinc pyrithione), 14-17 (basic zinc carbonate), 18 (cationic deposition polymer), 19 (conditioning agent), 20 (suspending agent) and 23-25 (methods of treating microbial infections, fungal infections and dandruff).

One of ordinary skill in the art would have recognized that the instantly claimed subject matter is encompassed by the material in the co-pending application. Since the

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compositions are the same then their properties would inherently be the same and the selection of crystallites of the particulate zinc material of less than about 600 angstroms is deemed merely a matter of judicious selection and routine optimization which is well within the purview of one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

III. Claims 1, 7, 8, 10, 11 and 14-16 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 11-13 and 17-19 of copending Application No. 10/392,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention embrace or are embraced by the claims in the co-pending application as is shown in the claims analysis table below.

Instant Application 10/802,166	Common claim elements	Co-pending Application 10/392,422 (03/18/2003)
1, 10 and 11	Zinc containing material; surfactant; pH greater than about 7; zinc lability greater than about 15%	1 and 5
1 and 14	Zinc-containing layered material	1 and 11
1 and 15	Zinc carbonate	1 and 12
1 and 16	Zinc carbonate	1 and 13
1 and 7	surfactants	1, 17 and 18
1 and 8	Anionic surfactant	1 and 19

One of ordinary skill in the art would have recognized the obvious overlap in scope of the instantly claimed invention and the co-pending application as set forth in the table above. Since the compositions are the same they would inherently have the same properties of solubility recited in co-pending application claim 1. The addition of water and adjustment of pH is made obvious by the disclosure of Bowser et al. (US 5,723,112) (Column 5, lines 9-12 and column 6, line 58 (Examples 1 and 2), for example). The adjustment of the amount of water added and the pH of the final composition is deemed merely a matter of judicious selection and routine optimization which is well within the purview of one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

IV. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-15, 17-22 and 26-32 of copending Application No. 11/216,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention embrace or are embraced by the claims in the co-pending application as is shown in the claims analysis table below.

Instant Application 10/802,166	Common claim elements	Co-pending Application 11/216,520 (08/31/2005)
1-3	Zinc material; zinc pyrithione; anionic surfactant; zinc lability 15%	1-3
4 and 6	Anionic surfactant	6 and 8
5	Zinc pyrithione 0.01 to 5%	7
7	surfactants	9

Instant Application 10/802,166	Common claim elements	Co-pending Application 11/216,520 (08/31/2005)
8	Anionic surfactant	10
9	pH greater than 6.5	11
10	pH from about 6.8-9.5	12
11	pH from about 6.8-8.5	13
12	Zinc lability 20%	14
13	Zinc lability 25%	15
14-17	Zinc carbonate	17-21
18	Cationic deposition polymer	22
19	Conditioning agent	26
20	Suspending agent	27
21 and 22	Crystalline suspending agent	28 and 29
23	Method of treating microbial infection	30
24	Method of treating fungal infection	31
25	Method of treating dandruff	32

One of ordinary skill in the art would have recognized that the comprising language used in the instant application does not preclude the addition of a zinc binding material and therefore the claim elements of instant claim 1 are made obvious by the co-pending application especially when the particulate zinc material is an inorganic material (claim 16) which is a zinc-containing layered material (claim 17) which is basic zinc carbonate (claims 18-21). Bowser et al. (US 5,723,112) suggests the addition of buffering or pH adjusting agents (Column 6, line 29) and suitable pH adjusting agents known in the art include citric acid as suggested by Cardin et al. (US 5,104,645) (column 10, lines 55-56). The specification of 11/216,520 points out that citric acid can be a zinc binding material (page 11, lines 3-6). The amount of zinc binding material added is deemed merely a matter of routine optimization, which is well within the purview of one of ordinary skill in the art.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

V. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 8-28 of copending Application No. 11/100648. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention embrace or are embraced by the claims in the co-pending application as is shown in the claims analysis table below.

Instant Application 10/802,166	Common claim elements	Co-pending Application 11/100,648 (04/07/2005)
1 and 18	Zinc material; surfactant; cationic polymer; zinc lability greater than 15%	1
2	Metal salt pyrithione	2
3	Zinc pyrithione	3
4	anionic	8
5	Zinc pyrithione	9
6	surfactant	10
7	surfactants	11
8	Anionic surfactant	12
9-11	pH greater than 6.5; pH from about 6.8-9.5	13-15
12 and 13	Zinc lability	16 and 17
14	Zinc carbonate	18
15-17	Zinc carbonate	19-21
19	Cationic deposition polymer	22
20	Conditioning agent	23
21 and 22	Suspending agent	24 and 25
23	Method of treating microbial infection	26
24	Method of treating fungal infection	27
25	Method of treating dandruff	28

One of ordinary skill in the art would have recognized that the copending application is an obvious variation of the instant invention as the instant claims elements encompass or are encompassed by the copending claims as set forth in the table above. Furthermore, the disclosure of Bowser et al. (US 5,723,112) suggests the addition of cationic polymers and control of the pH (Column 4, lines 62-67 and column 5, lines 1-30). The adjustment of particular working materials (i.e., a cationic polymer that has a trimethylamine level of less than about 45 ppm) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

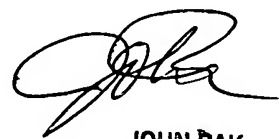
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA



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